



# Electronic Information Disclosure Statement

## Microneedle Devices and Methods of Manufacture and Use Thereof

Application:



10/010723

Confirmation: 4309

Applicant(s): Mark Allen

Docket

BVTP-P04-506

Number:

Group Art

3763

Unit:

Examiner:

Thompson, Kathryn L.

search string:

( 4320758 or 4664651 or 4671288 or 4703761 or 4775361 or 5035711 or 5147355 or 5599302 or 5605662 or 5611942 or 5632957 or 5758505 or 5807375 or 5848991 or 5852495 or 5855801 or 5858188 or 5865786 or 5865796 or 5876675 or 5883211 or 5885211 or 5899880 or 5911223 or 5919159 or 20010053891 ).pn.

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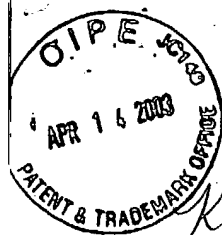
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## US Patent Documents

Note: Applicant is not required to submit a paper copy of cited US Patent Documents

init	Citation No.	Patent Number	Date	Bar Code	Patentee	Class	Subclass
	P01	4320758	1982-03-23		Eckenhoff et al.		
	P02	4664651	1987-05-12		Weinsbenker et al.		
	P03	4671288	1987-06-09		Gough		
	P04	4703761	1987-11-03		Rodion et al.		



P05	4775361	1988-10-04	Jacques et al.
P06	5035711	1991-07-30	Aoki et al.
P07	5147355	1992-09-15	Friedman et al.
P08	5599302	1997-02-04	Lilley et al.
P09	5605662	1997-02-25	Heller et al.
P10	5611942	1997-03-18	Mitsui et al.
P11	5632957	1997-05-27	Heller et al.
P12	5758505	1998-06-02	Dobak et al.
P13	5807375	1998-09-15	Gross et al.
P14	5848991	1998-12-15	Gross et al.
P15	5852495	1998-12-22	Parce
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P17	5858188	1999-01-12	Soane et al.
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P19	5865796	1999-02-02	McCabe
P20	5876675	1999-03-12	Kennedy
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P22	5885211	1999-03-23	Eppstein et al.
P23	5899880	1999-05-04	Bellhouse et al.

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P24	5911223	1999-06-15		Weaver et al.
P25	5919159	1999-07-06		Lilley et al.

## Published Applications

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init	Citation No.	Patent Number	Date	Bar Code	Patentee	Class	Subclass
740	U01	20010053891	2001-12-20		Ackley		

## Remarks

(Remarks are not for responding to an office action.)

This is Part One of a two-part Information Disclosure Statement. Part Two, citing non-U.S. Patent art, was filed this same day via First Class Mail. While the information and references disclosed in this Information Disclosure Statement may be "material" pursuant to 37 CFR 1.56, it is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such. In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists. Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents should one or more of the documents be applied against the claims of the present application.

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Substitute for form 1449A/PTO			<b>Complete if Known</b>		
			Application Number	10/010723	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)			Filing Date	December 6, 2001	
			First Named Inventor	Mark G. Allen	
			Art Unit	3763	
			Examiner Name	Thompson, Kathryn L.	
Sheet	1	of	4	Attorney Docket Number	BVTP-P04-506

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
KJL	AA	2,893,392	07/07/1959	Wagner et al.	
	AB	3,034,507	05/15/1962	McConnell et al.	
	AC	3,086,530	04/23/1963	Groom	
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Examiner Signature	<i>Kathryn L. Thompson</i>	Date Considered	04/12/2004
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		Art Unit	3763		
Sheet	2	of	4	Examiner Name	Thompson, Kathryn L.
				Attorney Docket Number	BVTP-P04-506

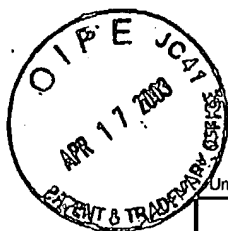
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FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Country Code <sup>2</sup> -Number <sup>4</sup> -Kind Code <sup>3</sup> (if known)					
KAY	BQ	EP 0497620		05/08/1992	Carnegie-Mellon University		
	BR	EP 0 652 600		5/1995			
	BS	JP 7132119		05/23/1995	Nikon Corp.		
	BT	JP 7196314		08/01/1995	Maruo Calcium Co., Ltd.		
	BU	WO 93/17754		09/16/1993	Elan Medical		
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	BY	WO 97/07734		03/06/1997	Spectrx, Inc.		
	BZ	WO 98/00193		01/08/1998	Altea Technologies		
	CA	WO 98/00194		01/08/1998	Sontra Medical		
	CB	WO 98/28037		07/02/1998	Alza Corporation		
	*CC	WO 00/48669		08/24/2000	Biovalve Technologies		
	*CD	WO 00/74763		12/14/2000	Georgia Tech Research		

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See attached Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the application number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. \* Applicant is to place a check mark here if English language Translation is attached.

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
KAY	*CE	Abrams, S.B. Versatile biosensor is compact and cheap. Biophotonics International 32-34 (Jan/Feb 1998).	
	CF	Amsden, B.G. and Goosen, M.F.A. Transdermal Delivery of Peptide and Protein Drugs: an Overview. AIChE J. 41, 1972-1977 (Aug. 1995).	
	CG	Brumlik, C.J. and Martin, C.R. Template Synthesis of Metal Microtubules. J. Am. Chem. Soc. 113, 3174-3175 (1991).	
	*CH	Chun, K. et al. Fabrication of Array of Hollow Microcapillaries Used for Injection of Genetic Materials into Animal/Plant Cells. Jpn. J. Appl. Phys. 38, 279-281 (1999).	
	*CI	Clarke, M.S.F. and McNeil, P.L. Syringe loading introduces macromolecules into living mammalian cell cytosol. J. Cell. Sci. 102, 533-541 (1992).	
	CJ	Despont, M. et al. High-Aspect-Ratio, Ultrathick, Negative-Tone Near-UV Photoresist for Mems Applications. IEEE 0-7803-3744-1/97 (1997).	
	CK	Edell, D.J. et al. Factors Influencing the Biocompatibility of Insertable Silicon Microshafts in Cerebral Cortex. IEEE Transactions on Biomedical Engineering 39, 635-643 (1992).	
	Examiner Signature: <i>Kathryn L. Thompson</i>		



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Sheet	3	of	4	Attorney Docket Number	BVTP-P04-506

*CL	Eleventh Annual International Workshop on Micro Electro Mechanical Systems, Heidelberg, Germany (25-29 Jan. 1998). IEEE Catalog No. 98CH36176
CM	Frazier, A.B. and Allen, M.G. Metallic Microstructures Fabricated Using Photosensitive Polyimide Electroplating Molds. J. Microelectromechanical Systems 2, 87-94 (June 1993).
CN	Frazier, A.B. et al. Two Dimensional Metallic Microelectrode Arrays for Extracellular Stimulation and Recording of Neurons. IEEE 0-7803-0957 pp. 195-200 (Feb. 1993).
CO	Haga et al. Transdermal Iontophoretic delivery of insulin using a photoetched microdevice. J. Controlled Release 43, 139-149 (1997).
CP	Hashmi, S. et al. Genetic Transformation of Nematodes Using Arrays of Micromechanical Piercing Structures. BioTechniques 19, 766-770 (Nov. 1995).
CQ	Henry et al. Microfabricated Microneedles: A Novel Method to Increase Transdermal Drug Delivery. J. Pharm. Sci. 87, 922-925 (1998).
CR	Henry, S. et al. Micromachined Needles: A Novel Approach to Transdermal Drug Delivery. J. Pharm. Sci. 87, 922-925 (Aug. 1998).
CS	Hoffert, S.P. Transcutaneous Methods Get Under the Skin. The Scientist 12, no. 16 (17 Aug. 1998).
*CT	Infiltrator Intramural Drug Delivery: A New Generation of Drug Delivery Catheters from InterVentional Technologies, Inc., San Diego, CA (1997).
CU	Jaeger, R.C. Introduction to Microelectronic Fabrication in the Addison-Wesley Modular Series on Solid State Devices, G.W. Neudeck and R.F. Pierret, eds. Vol. 5, Addison-Wesley Publishing Co., Inc. (May 1993).
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CY	Lehmann, V. Porous Silicon - A New Material for MEMS. IEEE ISBN: 0-7803-2985-6/96 (1996).
CZ	Lin, L. et al. Silicon Processed Microneedles. The 7 <sup>th</sup> International Conference on Solid-State Sensors and Actuators (1993).
DA	Martin, C.R. et al. Template Synthesis of Organic Microtubules. J. Am. Chem. Soc. 112, 8976-8977 (1990).

Examiner Signature	Kathryn L. Thompson	Date Considered	09/12/2004
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DB	Najafi, K. and Hetke, J.F. Strength Characterization of Silicon Microprobes in Neurophysiological Tissues. IEEE Transactions on Biomedical Engineering 37, 474-481 (May 1990).
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DD	<u>Percutaneous Absorption</u> , R.L. Bronaugh and H.I. Maibach, eds. Marcel Dekker, Inc., New York (1989).
DE	Prausnitz, M.R. Reversible Skin Permeabilization for Transdermal Delivery of Macromolecules. Critical Reviews in Therapeutic Drug Carrier Systems 14, 455-483 (1997).
DF	Proceedings of the IEEE Micro Electro Mechanical Systems Conference 1987-1998; Rai-Choudhury, ed., Handbook of Microlithography, Micromaching & Microfabrication (SPIE Optical Engineering Press, Bellingham, WA 1997).
DG	Quan, M. Plasma etch yields microneedle arrays. Electronic Eng. Times, p.63 (13 July 1996).
*DH	Reiss, S.M. Glucose- and Blood-Monitoring Systems Vie for Top Spot. Biophotonics International p. 43-46 (May/June 1997).
DI	Runyan, W.R. and Bean, K.E. <u>Semiconductor Integrated Circuit Processing Technology</u> , Addison-Wesley Publishing Co. (1990).
DJ	Schift, H. et al. Fabrication of replicated high precision insert elements for micro-optical bench arrangements. SPIE Vol. 3513, p.122-134 from SPIE Conference on Microelectronic Structures and MEMS for Optical Processing IV, Santa Clara (Sept. 1998).
DK	Single-crystal whiskers. Biophotonics Int'l, p. 64 (Nov./Dec. 1996).
DL	Talbot, N.H. and Pisano, A.P. Polymolding: Two Wafer Polysilicon Micromolding of Closed-Flow Passages for Microneedles and Microfluidic Devices. Solid-State Sensor and Actuator Workshop, Hilton Head Island, SC (8-11 June 1998).
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DN	Trimmer, W. et al. Injection of DNA into Plant and Animal Tissues with Micromechanical Piercing Structures. IEEE Catalog No. 95CH35754, ISBN: 0-7803-2503-6 from Micro Electro Mechanical Systems, Amsterdam p. 111-115 (1995).
DO	Weber, L. et al. Micro molding - a powerful tool for the large scale production of precise microstructures. SPIE No. 0-8194-2277-0/96, Vol. 2879, p.156-167 (1996).
DP	Zuska, P. Microtechnology Opens Doors to the Universe of Small Space. MD&DI (1997).

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